NCDENR
North Carolina Department of Environment and Natural Resources
Division of Environmental Health

Beverly Eaves Perdue
Governor

Terry L. Pierce
Director

Dee Freeman
Secretary

April 12, 2010

Edward J. Markey, Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6155

Dear Chairman Markey:

This letter is in response to your letter dated March 18, 2010, requesting information regarding North Carolina's regulation of medical patients being treated and released with therapeutic quantities of Iodine-131. Attachment 1 addresses your specific questions point-by-point. Please note that many of the answers reference rules found in 15A NCAC 11, *North Carolina Regulations for Protection Against Radiation*. The current regulations can be found on the agency Web site at: www.ncradiation.net.

The authority to regulate the safe use of radioactive materials falls under the Radioactive Materials Branch, which is part of the N.C. Department of Environment and Natural Resources, Division of Environmental Health, Radiation Protection Section. This authority is granted through an agreement between North Carolina and the federal government pursuant to Section 274 of the Atomic Energy Act of 1954, as amended. The state's performance of this agreement is inspected for adequacy and compatibility every two years by the U.S. Nuclear Regulatory Commission. North Carolina has always been found to have the highest performance under this agreement. The Radiation Protection Section not only oversees the regulation of radioactive materials licensees and registrants, but it also regulates accelerators, X-ray devices, tanning equipment and certain naturally-occurring radioactive materials.

If you need additional information or further clarification, please do not hesitate to contact either me at (919) 571-4141, ext 201, or at lee.cox@ncdenr.gov, or James Albright at (919) 571-4141, ext 250, or at james.albright@ncdenr.gov. Thank you for the opportunity to respond and for your concern for the health and safety of the citizens of this great nation.

Sincerely,

W. Lee, Cox, III, Chief
N.C. Radiation Protection Section

WLC/gas/jda
enclosure

ATTACHMENT 1

Question 1:
How many iodine-131 (1-131) licensee facilities are overseen by your State?

Response 1:
North Carolina has 33 licensees that are authorized to use Iodine 131 in therapeutic quantities greater than 33 millicuries.

Question 2:
How often does your State perform sampling inspections at each of these 1-131 licensee facilities?

Response 2:
North Carolina Radiation Protection Section staff inspects its medical licensees that administer therapeutic doses of I-131 every two to three years. Inspection frequencies are based upon the type and scope of the program, and are at least as frequent as required by the NRC's Inspection Manual Chapter 2800 (IMC 2800).

Question 3:
What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Response 3:
North Carolina follows all NRC applicable guidance outlined in Inspection Manual Chapter 2800 (IMC 2800) and NUREG 1556, Volume 9, Revision 2, Appendix U. This includes the inspection criteria for a facility requiring written directives, including those facilities that administer 1-131, in Inspection Procedure (IP) 87131 "Nuclear Medicine Programs, Written Directive Required." You will find in attachment 2 to this response a copy of the inspection field notes that are used for hospital nuclear medicine inspections. There are similar inspection field notes for medical board licensees and private practice nuclear medicine licensees. Inspectors determine that the licensee is knowledgeable about patient release criteria and is in compliance with the North Carolina patient release criteria in 15A NCAC 11 .0358 by direct observations and, if needed, by review of selected records. Inspectors also verify that the licensee's evaluation for release of the patient meets the requirements in 15A NCAC 11 .0358. The RPS expectations are that patient release criteria are consistent with those in the NRC Regulatory Guide 8.39, *Release of Patients Administered Radioactive Materials*. The inspectors review a sample of the licensee's written instructions to the patient to determine if the instructions meet current requirements.

Question 4:
NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients"[1]. For a patient receiving 175 millicuries of 1-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

Response 4:
North Carolina would instruct licensees during the licensing application process if they had questions, to refer to NUREG 1556 and 15A NCAC 11.0358. North Carolina's dose limits and restrictions are required to be compatible with the NRC's. There are several levels of compatibility: A, B, C, D and H&S. The higher the level (i.e. A being highest), the less flexibility there is in adopting that section of the regulation. The patient release criteria has a "C" compatibility rating. That rating requires "the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met." NC has adopted the same requirement as NRC and are not more restrictive. Those compatible requirements may be found in 15A NCAC 11 .0358.

Question 5:
In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?

Response 5:
During every inspection of medical use facilities using therapeutic quantities of I-131 that require a determination of whether to release the patient under 15A NCAC 11 .0358, inspectors evaluate the licensee's patient release program to verify compliance with North Carolina requirements. This includes determining if the licensee is knowledgeable about release criteria, maintains appropriate records to document the basis for authorizing the individual's release, and provides adequate instructions to patients. Further documentation is requested if deficiencies are noted. These documents are reviewed at the licensee's site during the inspection. The agency does not keep a specific record of how many times inspectors have requested such records; however, every inspection includes a random review of individualized release analysis. This review is documented on Attachment 2 under Iodine Therapy Administrations.

Question 6:
In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

Response 6:
North Carolina does not require licensees to keep a copy of the instructions provided to patients with the patient's record, although many of them do. These instructions are signed by the patient acknowledging the release conditions according to the instructions. During inspections, the inspector reviews a representative sample of cases for compliance. If the licensee does not keep copies of instructions for each patient or appropriate instruction models are not available at the licensee's facility the inspector will interview staff. The inspector will determine if the licensee is knowledgeable about release criteria and communicating adequate instructions to patients to determine if the licensee is in compliance with the regulations. The release guidance and instructions to patients are required as part of the application process prior to an applicant receiving their license to use I-131. North Carolina does not keep a specific record of how many times inspectors have requested I-131 patient release records.

Question 7:
In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Response 7:
In the past 10 years, North Carolina has not found any cases in which a required dose calculation was not performed by the licensee or the licensee did not provide written instructions to the patient on how to maintain doses to other individuals as low as reasonably achievable. In all cases reviewed, the licensees have demonstrated that the patients were allowed to be released per 15A NCAC 11 .0358.

Question 8:
In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 8:
It has been the experience of this agency that licensees are capable of calculating conservative dose estimates using reasonable assumptions concerning occupancy and other factors, using guidance in appropriate documents. The Radiation Protection Section also acknowledges that once patients are released, it is impossible for licensees to control patients' activities even though the licensee has provided all required release instructions.

Question 9:
Has your State ever attempted to determine how many patients treated with 1-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

Response 9:
North Carolina does not maintain records regarding the destinations of released patients from medical institutions. Instead, during on-site inspections at medical facilities, inspectors review a representative sample of cases involving therapeutic uses of radioactive materials to determine from patient records the circumstances whereupon the patient was released and content of the counseling the patient received. These reviews are used to verify compliance with the regulations regardless of the patient's final or interim destinations.

Question 10:
In patients with doses in excess of the default limits, has your State ever attempted to determine whether these 1-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

Response 10:
As discussed in previous responses, North Carolina inspectors evaluate the licensee's program for patient release to verify compliance with North Carolina requirements. Included in this evaluation is a review of the licensee's process for performing individualized analysis, including patient-specific calculations. The agency has found no situations where the dose calculations were not performed.

Question 11:
What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

Response 11:
North Carolina does not have disclosure rules or requirements for disclosure for patients administered I-131 to give to hotels. Instead, it is recommended that licensees refer to the NRC's guidance for medical use licensees, which contains general objectives rather than prescriptive directions. North Carolina requires the instructions to include actions the licensee recommends that meet the general objective of maintaining doses to other individuals as low as reasonably achievable, but licensees are not required to give patients explicit instructions to provide to hotel management. Guidance in NUREG-1556, Volume 9, Revision 2, Appendix U, describes in general terms how licensees can meet this performance-based objective. This document is reviewed and updated periodically by the NRC, and the Radiation Protection Section makes necessary changes to the program and inspection expectations at that time if necessary.

Question 12:
Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels: If so, please provide copies.

Response 12:
North Carolina has not issued advisories or guidance specific to warning licensees not to send radioactive patients to hotels; however, the agency routinely sends licensees information notices regarding other topics as applicable.

Question 13: Are your licensees required to report to you any instances in which released I-131 patients caused radiation exposure to family members or members of the public?

Response 13:
North Carolina does not require such a report. Once a patient is released under 15A NCAC 11 .0358, there are no further reporting requirements for either the patient or licensee.

Question 14: Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclides.

Response 14:
The only correspondence between North Carolina Radiation Protection Section and the NRC related to release of patients treated with radionuclides is the routine review of the agency through the Integrated Materials Performance Evaluation Program (IMPEP). These reports can be found on the NRC's Web site as follows: http://nrc-stp.ornl.gov/reviews.html#NC.

Question 15:
Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Response 15:
If documents required under 15A NCAC 11 .0358 are missing or incomplete, then it is considered to be a violation of North Carolina requirements and would be identified and cited as such by inspectors. If the documentation is initially unclear, the inspector will ask additional questions to determine if a violation has occurred or not. Therefore, it is reflected in the inspection report accordingly. North Carolina has no report indicating documents relating to patient release were found to be missing, inadequate or unclear. There are no known cases where patients went to a hotel in North Carolina.

NCDENR
North Carolina Department of Environment and Natural Resources

ATTACHMENT 2
RADIOACTIVE MATERIALS BRANCH
INSPECTION FIELD NOTES

HOSPITAL-BASED NUCLEAR MEDICINE

License No.: 000-0000-0

Licensee: **Address:**	**License No.:** **Amendment No.:**

Inspection Type	**Inspection Scope**	**Inspection Frequency**
Home Office ☐ Investigation ☐ Other ☐	Full ☐ Limited ☐ *Partial ☐ (*Does not alter inspection due date)	Normal ☐ Re-inspect in ____ months
Explain:	Comments:	Comments:

Inspector(s): Radiation Safety Officer: Licensee Representative	Date(s) of Inspection: Telephone ( ) - **Facsimile** ( ) - **e-mail** Telephone ( ) - **Facsimile** ( ) - **e-mail**

Organization ***(Management, Authorized Users, Technologists, Training, etc.)***

President/CEO
Vice President
Radiology Manager

Authorized Users: [.0117 & 10 CFR 35 Subpart J by reference]

Name	On Lic. or RSC approval	Name	On Lic. or RSC approval

Visiting Physicians [L.C.]

Name	Admin & RSC Approvals	Listed on another NC License?

Technologists [.0318]

Name	Training (ARRT or CNMT or OJT)	Certification available?

Physicist/Consultant:

Date of Last Inspection Previous Noncompliance Status:	Inspector(s)

Radiation Safety Committee ***(membership, meeting dates, etc.) [.0319]***

Membership:

Administration	RSO	Nursing	Other Dept.	Other Dept.

Meeting dates [L.C.]

Program: ***(patient frequency, in-services, misadministrations, recordable events, etc.)***

Patient frequency
Technologist In-services [.0318]
Ancillary Personnel In-services
Misadministrations?
Recordable events?

Radionuclides ***(isotope, form, quantities allowed, etc.) [L.C.]***

Isotope	Form	Quantity
Groups I – IV	As listed in Pub 97-01	As necessary

Unit doses or generators? (pharmacy name)

Records / Written Procedures: ***(receipt, use, PWA, APR, QMP review, etc.)***

SOP's [L.C.]
Emergency [L.C.]
Misadministration [.0350]
DPW [.1610]
Bioassay proc. (w/ dose summation)
^{131}I therapy proc. (surveys, waste, etc.)
Patient release criteria [.0358]
Receipt [.1627]
- ➢Written Procedures on file?
- ➢Swipe
- ➢1 meter

Returns [L.C.]
- ➢Written Procedures on file?
- ➢Swipe
- ➢1 meter

Prior written approval [.0104(146)]
"Use Logs" (Content) [.0356(f)(2)]
APR (contents, dates, etc.) [.1603]
QMP review (contents, dates, etc.) [.0356]
- ➢Two (2) types of ID
- ➢Annual Review
- ➢Recordable Events
- ➢PWA

DCPM signed by an AU? [.0104(35)]
Molybreakthrough [.0361]
Waste handling/disposal procedures

DOT ***(shipping papers, marking, labeling, containers, etc.): [.0117 & 49 CFR]***

Shipping papers adequate?
Return shipments appropriately marked/labeled
TYPE A container condition:
Package closures?
Surveys on returns
- ➢Swipe
- ➢1 meter

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RADIOACTIVE MATERIALS BRANCH
INSPECTION FIELD NOTES

HOSPITAL-BASED NUCLEAR MEDICINE

License No.: 000-0000-0

NOTE: 49 CFR 173.421 states that LQ shipments are exempted from most of the requirements of marking, labeling and shipping papers. LQ shipments MUST meet exposure rate on surface < 0.5 mrem/hr and, <22 dpm/100cm^2 removable contamination. MUST have the statement that "This package conforms to the conditions and limitations ...excepted package-limited quantity of material, UN2910" OR, if empty "This package conforms to the conditions and limitations...excepted package-empty package, UN2910."

Waste Disposal ***(methods, records, etc.) [.0362, .1628, L.C.]***

Method(s):
Records:
Ordinary Trash check? [L.C.]

Use Area & Security ***[.1622 & L.C.]***

Operating Hours:
Key Control:
Housekeeping access?
Courier/Pharmacy access?

Licensee Surveys ***(location, frequency, methods, instrumentation, records, etc.)***

Daily GM Surveys:
➢Trigger levels estab? [.0360]
Weekly wipes:
➢Trigger levels estab? [.0360]
.1611 surveys?

Instrumentation ***(make, model, s/n, etc.)***

Make	Model	Serial No.	Range	Calibration dates

Inspector's Survey (See attached)

Instrument Used	Calibration date	Serial No.

Leak Testing & Physical inventory ***(frequency, by whom, results)***

Leak Testing

Source ID	Dates	By Whom	< 0.05 µCi

Physical Inventory

Source ID	Dates	By Whom	Location

Personnel Dosimetry ***(supplier, frequency of exchange, DPW records, RSO review of exposures, etc.) [.1604, .1613]***

Supplier: NVLAP certified? Exchange Frequency:
RSO Review? Any DPW's?

	Total mrem for			Total mrem for		
Personnel:	Deep	Shallow	Extremity	Deep	Shallow	Extremity

Posting & Labeling:

Section .1000 requirements

Posing of use areas correct?
Posting of storage areas correct?
Regulations available?
License available?
Application available?

Imaging/ Scanning/Uptake ***(make model, QA frequency, calibration, MDA, etc.) [L.C.]***

Camera(s)

Make	Model	Daily Floods	Weekly Bars	COR

Uptake Probe(s)

Make	Model	Serial No.	Calibration	MDA

Xenon / DTPA aerosol studies ***(clearance times, self-contained collection unit, shielded units, etc.) [.0361]***

Xenon
Make/Model of Unit — Clearance times posted?
Hood for multi-dose vial storage? — Air changes checked every 6 months? [L.C.]
DTPA
Make/Model of Unit — Self-contained unit?

Dose Calibrator information ***(make, model, QA freq., etc.) [.0359]***

Make	Model	Serial No.

Constancy	Dates:		By:		Findings:	
Linearity	Dates:		By:		Findings:	
Accuracy	Dates:		By:		Findings:	
Geometry	Dates:		By:		Findings:	

Iodine Therapy Administrations ***(PWA, bioassay, surveys, release criteria, etc.) [.0358 & L.C.]***

	Patient 1	**Patient 2**	**Patient 3**
Administration date			
Technologist(s) involved			
Physician(s) involved			
Form (liq. or capsules)			
Dose administration:			
➢Where			
➢Who present			
Bioassays			
➢procedures on file?			
➢baselines			
➢within 72 hr. of admin.			
➢instrumentation used			
➢action levels estab.?			
➢review by RSO			
Surveys:			
➢patient survey @ 1 m			
➢frequency			
➢1611/12 survey			
➢release survey(s)			
Room postings adequate?			

Nursing Instructions avail? Dosimetry for nursing staff NOTES:			
No. of ablative therapies / yr.			
Additional Information:			
Exit Interview Summary:			
Attendees: Summary:			

Inspector's survey

Apparent Items of Noncompliance/Unresolved Issues/Non-cited violations/Recommendations

The following are my/our findings regarding the foregoing inspection. I/we believe that the factual information contained in this report support these findings.

Signature _____ Date _____

Signature _____ Date _____

Items of Noncompliance:
1.
2.
Unresolved Issues:
1.
2.

☐ Subsequent to review of this report, I agree that the findings outlined above appear to be valid and well-supported and may be passed to the licensee

_____ _____
Reviewed By Review Date

☐ Subsequent to review of this report, I disagree with the findings as follows: Findings shall not be passed to the licensee until comment(s) outlined below are resolved:

_____ _____
Reviewed By Review Date

COMMENT RESOLUTION:

1. Comment	1. Resolution
2. Comment:	2. Resolution
3. Comment	3. Resolution